

REMARKS

The above claim amendments are submitted along with the following remarks to be fully responsive to the outstanding non-final Office Action mailed December 22, 2006. It is further submitted that this response is timely filed within the three month shortened statutory period. Reconsideration of all outstanding grounds of objection and rejection and allowance of the subject application are respectfully requested. Although no fees are believed to be due, the Commissioner is authorized to charge any additional fees or credit any overpayment to Kagan Binder deposit account No. 50-1775 and notify us of the same.

Claims 42-49 and 51 were rejected under 35 U.S.C. §103(a) as being unpatentable over Uchigaki et al. (U.S. Patent No. 6,830,551) in view of Higgins et al. (U.S. Patent No. 4,545,382). As amended, independent claim 42 is directed to a method for determining the concentration of at least one target constituent contained within biological fluid, where the method includes a number of steps, including: providing at least one hollow micro-needle, providing an electrochemical cell in communication with the hollow micro-needle, inserting the micro-needle into the skin of a patient, transferring a fluid sample into the electrochemical cell, providing a first electrical signal to the electrochemical cell, and receiving a second electrochemical signal generated by the electrochemical cell. The hollow micro-needle comprises open distal and proximal ends and a lumen extending between them. As amended, the electrochemical cell includes an electrode configuration comprising a first electrode, a second electrode spaced apart from the first electrode, and a reaction zone between the first and second electrodes. This electrode configuration is positioned at the open proximal end of the micro-needle substantially transverse to the micro-needle. The reaction zone is in communication with the micro-needle.

Certain features of the electrochemical cell are described in paragraphs [0056-0057] of the publication of the present application (U.S. Patent Publication No. 2005/0261606) and are illustrated in Figures 2A and 2B. In particular, Figure 2A illustrates a lumen 220 extending from the tip 202 of micro-needle 200 toward its proximal end 205. Electrodes 208 and 212 make up an electrochemical cell, which is positioned at the proximal end 205 of the micro-needle in a direction that is transverse to the micro-needle. As illustrated and described, the electrode 208 is spaced from the electrode 212 by a spacing that functions as

a reaction zone 210, which extends from the lumen 220. As is further described in paragraphs [0060-0062], a transfer medium may occupy the reaction zone 210 at least a portion of the lumen 220, thereby providing the substance through which target constituents can move to reach the reaction zone 210. Thus, the lumen 220 is in communication with the reaction zone 210.

As described by the Examiner, Uchigaki et al. teach a method for determining the concentration of a constituent contained within biological fluid. However, the Examiner refers to the element 52 of Uchigaki et al. as a micro-needle or lancet comprising an open distal end and a space or lumen 52d, then also describes the *same* element 52 as being “an electrochemical cell” comprising a tube 52a, which acts as an active electrode, and axial core 52b, which acts as a counterpart electrode, with the electrodes being parallelly-spaced apart. The Examiner further states that Uchigaki et al. do not teach this electrode configuration 52a/52b as being substantially transverse to the micro-needle, but states that Higgins et al. do teach an electrochemical sensor electrode configuration 15 that is positioned transverse to a hypodermic needle 16. The Examiner then states that it would have been obvious to modify the electrode configuration 52a/52b of Uchigaki et al. to be transverse to its micro-needle in view of the disclosure of Higgins et al. Applicant respectfully disagrees. First, Higgins et al. do not disclose electrodes that are spaced from each other with a reaction zone between them, with a reaction zone being in communication with a lumen of a micro-needle, as in the present claim 42. In addition, any modification of the devices of Uchigaki et al. to change the positioning of their electrochemical cell would also necessarily change the positioning of their lancet, since the Examiner characterizes the lancet 52 and the electrochemical cell 52a/52b as the same element of their device. That is, because the micro-needle or lancet and electrochemical cell of Uchigaki et al. are the *same* element of their body fluid measuring apparatus, it follows that there is no teaching or suggestion in Uchigaki et al. to differently orient two distinct and independent elements relative to each other in a single device. Thus, Applicants respectfully request withdrawal of the rejection of claim 42. In addition, claims 43-49 and 51 are also believed allowable at least in that they depend from claim 42.

Claim 50, which depends indirectly from claim 42, was rejected under 35 U.S.C. §103(a) as being unpatentable over Uchigaki et al. in view of Higgins et al., as applied to

claim 42 above, and further in view of Kwon et al. (U.S. Patent No. 6,207,400). Because Kwon et al. do nothing to cure the deficiencies of Uchigaki et al., either alone or in combination with Higgins et al., claim 50 is believed allowable for the same reasons provided above.

Accordingly, it is submitted that presently pending claims 42-51 are currently in condition for allowance, a notice of which is earnestly solicited. If the Examiner finds any issue remaining after consideration of this response, the Examiner is invited to contact the undersigned, at the Examiner's convenience, in order to expedite any remaining prosecution.

Respectfully Submitted,

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By


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